Thomas J. Quinn
Consultant

May 3, 2001

Mr. Orthan H. Suleiman
Food and Drug Administration
CDRH
1350 Piccard Dr.
Rockville, MD 20850

VIA FACSIMILE/E-MAIL

Dear Mr. Suleiman:

Please accept this letter as a response to the issues before the Technical Electronic Product Radiation Safety Standards Committee (the Committee) scheduled for May 17, 2001.

It is the goal of most Americans to assure a safer environment for patients and others exposed to the inherent dangers of all medical devices.

The laws contained in various performance standards contained in 21CFR, under review by this Committee were enacted to accomplish that goal.

However, the natural evolution of laws being improved over time by resolving issues has not occurred in regards to the performance standards contained in 21CFR.

The lack of any meaningful enforcement action by CDRH, in regards to manufacturer's compliance with the performance standards, over the last twenty-seven years has prevented this natural evolution of the laws from occurring.

The Committee will conduct an informal review of these performance standards at the May 17, 2001 meeting. While this is a very commendable act by CDRH, it does not address the core problem.

Manufacturers of electronic devices have for years taken a two faced approach to the performance standards. While some manufacturers have repeatedly filed documents to gain clearance to sell and market their devices, verifying to CDRH that they will comply with the performance standards, the proof shows that many manufacturers did not and still will not fully comply with these standards.

CDRH has repeatedly and miserably failed in its duties to properly protect Americans from the inherent dangers of medical devices.

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The many programs and solutions attempted by CDRH, while appearing to be sound, actually wasted valuable resources in time and monies.

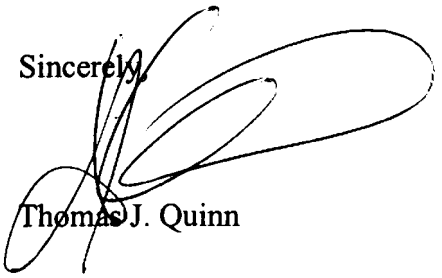
CDRH has not and is not likely to resolve the issues of safety of medical devices under the current structure.

Again, the need for a Citizens Advisory Committee, with representation from the true experts in this industry is the only solution to this problem.

CDRH's lack of support for this new Committee is not appropriate and ignores the most fundamental problems CDRH has consistently failed to address.

CDRH needs the input of Hospitals, ISO's, Consultants, Trade Groups, Asset Management Groups, and others, excluding manufacturers and their representatives, to assure the safety of medical devices. Only then, can the natural evolution of improving the laws governing all medical devices work to assure the long-term safety of all medical devices.

Sincerely,



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Cc President George W. Bush
Senator Arlen Specter
Secretary Tommy Thompson
Ms. Linda Kahan

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